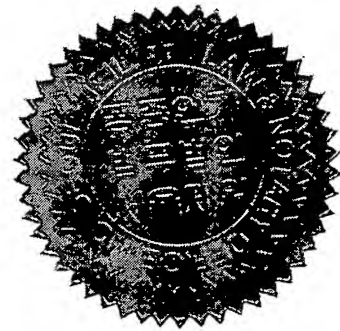


[제41호 서식]

Registered No.

2007 -2476

NOTARIAL CERTIFICATE



Law & Notary Office Inc. Seoul-Jeil

TEL : 568 - 4040

(19) Korea patent office (KR)
(12) Granted Patent Publication(B1)



(51) Int.Cl. C07H 3/00

(45) Examined Publication Date 2003-01-30 (Y/M/D)

(11) Registration No. 10-0369518

(24) Registration Date 2003-01-13

(21) Application No 10-2000-0005039

(65) Publication No 10-2000-0036332

(22) Application Date 2000-02-02

(43) Publication Date 2000-07-05

(73) Right Holder Gong-Su Kim
Seok-Hyeong Cho

(72) Inventor Seok-Hyeong Cho
Gong-Su Kim

(74) Agent Sang-Seop Jung

Examiner In-Gyeong Yu

(54) Title of Invention METHOD OF MANUFACTURING LOW MOLECULAR
POLYSACCHARIDE AND OLIGOSACCHARIDE THEREOF

Abstract

The present invention relates to method of efficiently manufacturing low molecular weight polysaccharide adding an optical catalyst like peroxide and the titanium dioxide and disassembling the polysaccharide by irradiating the light including the ultraviolet ray, the radiation, the electron beam etc. in the polysaccharide. The low molecular weight polysaccharide is the bioactive substance which extensively can be used food additions, the natural pesticide, a drug etc.

Representative Drawing(s)

FIG1.

Keyword(s)

The optical catalyst, chitosan, ultraviolet ray, radiation

Translated by

Jean-Win KIM



Statement

I, Jean-Won KIM; JINSUNG International Patent; A-302 Uga villa, 346-12 Gaebong-
dong, Guro-gu, Seoul 152-090, Republic of Korea , have a thorough knowledge of the
Korean and English languages and hereby certify that the attached English language
document is a true and accurate translation of the Korean Patent Registration No. 10-
0369518 (inventors: Cho et al.) into English.

On this, the 27th day of August , 2007

Jean-Won KIM

translator signature

Jean-Won KIM

translator name

위 번역문은 원문과 상위없음을
서약합니다.

2007 . 08. 27.

서약인 김진원 (인)

I swear that the attached translation
is true to the original.

27. Aug. , 2007

Signature Jean-Won KIM

등부 2007 년 제2476 호

Registered No. 2007 -2476

인 증

Notarial Certificate

위 김진원은
본직의 면전에서 위 번역문이
원문과 상위없음을 확인하고
서명날인하였다.

Jean Won, Kim
personally appeared before me
confirmed that the attached
translation is true to the original
and subscribed his(her) name.

2007 년 08 월 27 일
이 사무소에서 위 인증한다.

This is hereby attested on
this 27 day of Aug. , 2007
at this office.

서울시 강남구 역삼동 642번지19호
공증인가 법무법인 서울제일

Law & Notary Office Inc. Seoul-Jeil
642-19, Yeoksam-dong, Gangnam-ku,
Seoul, Korea.

공증담당변호사

Attorney-at-Law

Jin Seob Kim

This office has been authorized
by the Minister of Justice, the
Republic of Korea, to act as
Notary Public since Feb. 1th
2005, under Law NO.2005-4.

(19) Korea patent office (KR)
(12) Granted Patent Publication(B1)

(51) Int.Cl. C07H 3/00 (45) Examined Publication Date 2003-01-30 (Y/M/D)
(11) Registration No. 10-0369518
(24) Registration Date 2003-01-13

(21) Application No	10-2000-0005039	(65) Publication No	10-2000-0036332
(22) Application Date	2000-02-02	(43) Publication Date	2000-07-05

(73) Right Holder Gong-Su Kim
 Seok-Hyeong Cho

(72) Inventor Seok-Hyeong Cho
 Gong-Su Kim

(74) Agent Sang-Seop Jung

Examiner In-Gyeong Yu

(54) Title of Invention METHOD OF MANUFACTURING LOW MOLECULAR
POLYSACCHARIDE AND OLIGOSACCHARIDE THEREOF

Abstract

The present invention relates to method of efficiently manufacturing low molecular weight polysaccharide adding an optical catalyst like peroxide and the titanium dioxide and disassembling the polysaccharide by irradiating the light including the ultraviolet ray, the radiation, the electron beam etc. in the polysaccharide. The low molecular weight polysaccharide is the bioactive substance which extensively can be used food additions, the natural pesticide, a drug etc.

Representative Drawing(s)

FIG1.

Keyword(s)

The optical catalyst, chitosan, ultraviolet ray, radiation

Description

■ Brief Explanation of the Drawing(s)

Fig. 1 is a drawing showing the reduction of the molecular weight according to the time for dispersing the optical catalyst and disassembling a chitosan to the ultraviolet ray 254nm.

Fig. 2 is a drawing showing the reduction of the molecular weight according to the time for dispersing the optical catalyst and disassembling a chitosan to the ultraviolet ray 340nm.

Fig. 3 is a drawing showing the reduction of the molecular weight according to the time for dispersing the optical catalyst and disassembling a chitosan to the gamma-ray 10 kGy.

Fig. 4 is a drawing showing the reduction of the molecular weight according to the time for not dispersing the optical catalyst and disassembling a chitosan to the ultraviolet ray (254nm).

■ Details of the Invention

■ Purpose of the Invention

- The Technical Field to which the Invention belongs and the Prior Art in that Field

The present invention relates to the method of manufacturing low molecular weight polysaccharide adding an optical catalyst like peroxide and the titanium dioxide and disassembling the polysaccharide by irradiating the light including the ultraviolet ray, the radiation, the electron beam etc. in the polysaccharide. More, it relates to the method of manufacturing low molecular weight polysaccharide dispersing the polysaccharide into the solvent which is selected between the distilled water and acetic acid, agitating the solution in 5~50°; dispersing by adding the polysaccharide solution or powder to 0.01 through 5 weight% optical catalyst which is selected among the titanium oxide, the zinc oxide, the ferric oxide, the cadmium sulfide, the zinc sulfide, the hydrogen peroxide, and irradiating the light which is selected among the ultraviolet ray, α -ray, β -ray, the gamma ray, the electron beam etc.

Recently, the low molecular weight polysaccharide is expected wide application in the field of medicine and agricultural field. The ripple effect which brings it on overall life science is enormous. Particularly, the explanation of the biological function of the oligosaccharide of glycoprotein and glycolipid is connected to the medicine development and the new usage thereof. As to a plant, the structure of the oligosaccharide separated from the cell and the bio-defense active about microorganism infection etc. are clarified, thus the discovery of the new function of plant adjustment material and the usage at agricultural field are expected. Moreover, it can be extensively used in the field of the food, a cosmetic, a medicine, a reagent etc.

Conventionally, as to the method for obtaining the low molecule polysaccharide, the

enzymolysis or the acid-labile method of the polysaccharide had being performed. But the enzyme decomposition treatment has the disadvantage that the kind of a product is restricted because of specificity of the enzyme decomposition treatment and limited place for disassembling the polysaccharide. Moreover, in case of an acid-labile method, because the decomposition of the polysaccharide is comprised of the severe with the concentrated hydrochloric acid condition, it has the disadvantage that the conversion efficiency is low, a monosaccharide is very much generated, it is difficult to collect the excess used reagent and the environment problem is occurred.

The technology is presented in JP 10-101704 about the method for complementing these disadvantages and manufacturing the low molecule polysaccharide with the light.

But as to such prior art, the resolving time is mostly long and it is difficult efficiently to manufacture the low molecule polysaccharide.

If the compound used as the optical catalyst bumps against photon comes the energy called the $h\nu$ which is the same as that of the bandgap energy of the optical catalyst or bigger than this, while an electron comes from the valence band and it moves to the conduction band, consequently it leaves a hole in-situ. While again returning to the valence band, at this time electron in high level presents the energy as the heat. At this time, if the appropriate scavenger or surface defect state exists and the electron or the hole is trapped, the recombination does not achieve and the oxidation-reduction reaction occurs. The valence band hole is the powerful oxidizer and conduction band electron is good reducing agent. Most organic light decomposition reaction uses the oxidizing potential of a hole directly or indirectly. It has the titanium dioxide, the zinc oxide, the ferric oxide, the cadmium sulfide, the zinc sulfide, the nickel oxide, the cobalt oxide etc to use as the optical catalyst, and the titanium oxide is known as the material which is most suitable for the real application. As to the oxide titanium, the energy gap (3.2eV) is biologically stable, the corrosion does not occur and the price is very low.

• The Technical Challenges of the Invention

The present invention relates to method for efficiently manufacturing the low molecular weight polysaccharide, dissolving the polysaccharide in the appropriate a solvent including the distilled water etc. to the constant concentration, dispersing the titanium oxide, the zinc oxide, the ferric oxide, the cadmium sulfide, the zinc sulfide, the hydrogen peroxide etc into this solution or powder as the optical catalyst and irradiating the light including the ultraviolet ray (UV), a gamma-ray, the electron beam etc.

■ Structure & Operation of the Invention

The present invention relates to the method for manufacturing the low molecular weight

polysaccharide.

That is, it relates to the method of low molecule polysaccharide consisting of dissolving the polysaccharide at the appropriate a solvent including the distilled water etc. to the constant concentration, dispersing the titanium oxide, the zinc oxide, the ferric oxide, the cadmium sulfide, the zinc sulfide, the hydrogen peroxide etc into the solution or powder as the optical catalyst, and irradiating the light including the ultraviolet ray (UV), a gamma-ray, the electron beam etc.

According to the present invention, the polysaccharide could be the chitin, chitosan, pectin, inulin, cellulose, gum, starch, glycogen, heparin, alu phosphoric acid, poly-galactoss amine and their derivative etc. The concentration of the polysaccharide solution could be preferably 0.5~20 weight%, even if it uses 20 weight% or greater, moreover, it has no relation even if the solid is used.

As to the optical catalyst used in the present invention, titanium oxide, zinc oxide, ferric oxide, cadmium sulfide, zinc sulfide, the hydrogen peroxide etc., preferably the titanium oxide or the hydrogen peroxide is most appropriate. The amount of addition of the optical catalyst can use 0.01 through 5 weight%, preferably 0.05 through 1 weight% is appropriate.

As to the light used in the present invention, while using the ultraviolet ray and the radiation, if the ultraviolet ray can be appropriate it uses the thing of 200 through 400nm range and the radiation can use α -ray, β -ray, gamma ray, electron beam, preferably gamma ray and the electron beam are convenient. The dose of the electron beam can use 0.01 through 2,000kGy, preferably 100 through 2,000 kGy when using in the dehydrated state, and 0.01 through 20kGy while using in the solution state.

Method of manufacturing low molecule polysaccharide in the present invention, for example, the chitosan 5 parts by weight is dispersed into 1% acetate solution 100-200 parts by weight and it agitates in 5~50° ; thus it dissolves into solution. After dispersing 0.1 through 0.5 parts by weight the titanium dioxide into this solution, irradiating in the ultraviolet ray (high pressure mercury lamp) 254nm with the half an hour or 76 hour, thus the chitosan with low molecular weight was manufactured. Otherwisc, irradiating electron beam dose in 0.01 through 20 kGy with 1~76 hour at a rate per the chitosan solution described in the above, thus the low molecule polysaccharide was manufactured.

The present invention will now be described more fully, in which exemplary embodiments of the invention are shown.

Embodiment 1.

After the chitosan 50g being dissolved in 5% acetic acid aqueous solution 1000g and dispersing the titanium dioxide 1g into this solution, irradiating in the ultraviolet ray (high

pressure mercury lamp) 254nm with 1 through 76 hour, thus the chitosan pyrolysate was manufactured. The pyrolysate in the solution or the freeze-drying (in other words, the spray dry) of that can be used. The result was shown in Fig. 1. As shown in Fig. 1, irradiating 12 hours the decomposition occurs within the fast time to reduce to 20,00 molecular weight, while irradiating over 2 days to manufacture the oligosaccharide level. Moreover, the productivity was 100%, the effluent was not generated.

Embodiment 2.

Except irradiating the ultraviolet ray in 340nm, it performed to the same method as the embodiment 1 described in the above. When being lengthening the wavelength of the ultraviolet ray, Fig. 2 shows the resolving time was lengthened. Embodiment 2 was similar to the embodiment 1.

Embodiment 3.

Except irradiating a gamma-ray in 10kGy, it performed to the same method as the embodiment 1 described in the above. As shown in Fig. 3 a gamma-ray is used, it could be low-molecularized in a short time and the oligosaccharide could be manufactured in 2 times. But in case of using the radiation, it has the disadvantage that it requires the management expense with the reaction facility including the reaction chamber etc.

Embodiment 4.

Except using the carboxymethyl cellulose or the pectin, it performed to the same method as the embodiment 1 described in the above. In the case of changing the polysaccharide, the same result of embodiment 1 was obtained.

Comparative Example 1.

Except eliminating the titanium dioxide, it performed to the same method as the embodiment 1 described in the above. As shown in Fig. 4 compared with the embodiment 1, it is seen that when the optical catalyst does not use, the decomposition speed is slow, the production efficiency is low.

Embodiment 5.

While analyzing the molecular weight of the of which oligosaccharide and the pyrolysate obtained to above statement example 1-3, and the method of the Comparative Example 1 to G P C, used the Shodex OHpak SB-801+SB-802+ SB- 803 (7.5mm ID×300mm L) and while an effluent used 0.1M phosphate buffer solution, iadjusted a flux as 0.8 ml/min. The result is the

same like the Fig. 1, 2, 3, 4.

■ Effects of the Invention

It is seen that the rapid degradation speed is shown by adding the optical catalyst,, as shown in the embodiment described in the above and comparative example, it is the polysaccharide disassembled in the time to be short. As to the present invention, by using the oxide titanium in which the cost is inexpensive as a catalyst while rapidly efficiently manufacturing the low molecule polysaccharide in comparison with the conventional technology. The processing costs can be low and it can manufacture the polysaccharide of the desired molecular weight at a rate per the time to be short, thus it is more economic.

Scope of Claims

Claim[1] :

The method of manufacturing the low molecular weight polysaccharide, wherein
Dispersing 0.5~20 weight% polysaccharide into the solvent among the distilled water, acetic acid, agitating in 5~50° ;

Adding the solution or the polysaccharide powder 0.01 through 5 weight% optical catalyst selected from the group consisting of the titanium oxide, the zinc oxide, the ferric oxide, the cadmium sulfide, the zinc sulfide, and the hydrogen peroxide

Irradiating the light selected from the group consisting of the ultraviolet ray of 200 through 400nm range, α -ray, β -ray, the gamma ray, and the electron beam of 0.01 through 2,000kGy

Claim[2] :

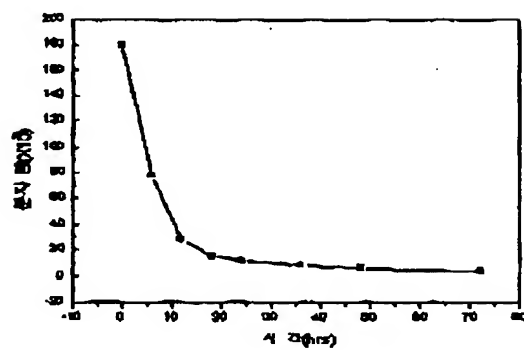
Deletion.

Claim[3] :

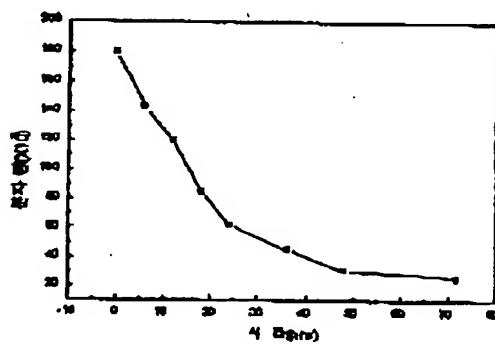
The method of manufacturing the low molecular weight polysaccharide of claim 1, wherein the polysaccharide is one selected from the group consisting of a pectin, a chitin, a chitosan, a inulin, a cellulose , a starch, a glycogen, a heparin, a phosphoric acid, and a poly galactoss amine.

Claim[4] :

Deletion.

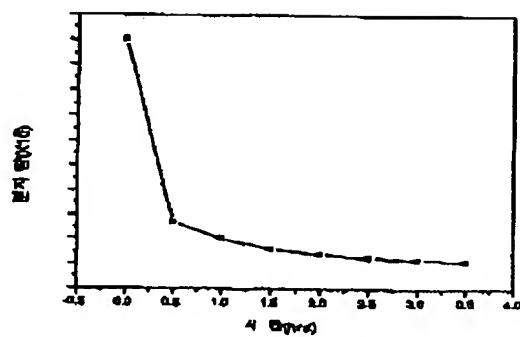
DRAWINGS**FIG1.**

x; time y: molecular weight

FIG2.

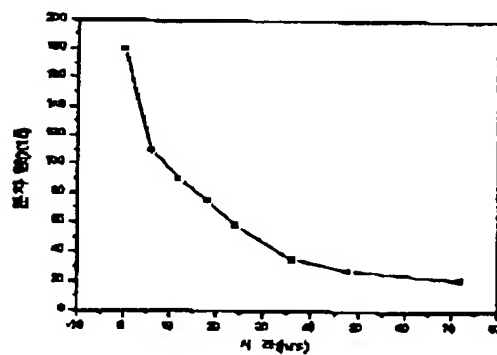
x; time y: molecular weight

FIG3.



x; time y: molecular weight

FIG4.



x; time y: molecular weight

11 of 248 DOCUMENTS

Ex parte JAMES U. MORRISON

Appeal No. 2004-1112

Application No. 09/829,707

Board of Patent Appeals and Interferences

2004 Pat. App. LEXIS 32

July 22, 2004, Decided

[*1]

Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

OPINIONBY: GRIMES

OPINION:

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

ON BRIEF

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 15-27 and 43. Claims 1-14 and 28-42 are also pending but have been withdrawn from consideration. Claims 15 and 43 are representative of the subject matter on appeal and read as follows:

15. A chemical composition used to stimulate weight loss in a patient, comprising:

acarbose; and

a sustained release matrix,

wherein said acarbose and sustained release matrix are combined to form a mixture.

43. A method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.

The examiner relies on the following references:

Bremer et al. (Bremer)	5,643,874	Jul. 1, 1997
Patel et al. (Patel)	6,309,663	Oct. 30, 2001
Rosner	6,387,361	May 14, 2002

[*2]

Claim 43 stands rejected under 35 U.S.C. § 102(a) as anticipated by Rosner. Claims 15-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bremer, and under 35 U.S.C. § 102(e) as anticipated by Patel.

We reverse all of the examiner's rejections and enter a new rejection of claim 43.

Background

"Acarbose is an oral alpha-glucoside [sic, glucosidase?] inhibitor approved for use in the management of non-insulin-dependent diabetes mellitus (NIDDM). Acarbose is [a] complex oligosaccharide that delays the digestion of ingested carbohydrates." Specification, page 4. "Acarbose . . . is marketed as an orally administered drug under the name Precose(R) and Glucobay(R). Both Precose(R) and Glucobay(R) are simply coated with a delayed release coating." Id., page 1.

The specification discloses that "sustained release products are widely recognized in the art and are of extreme importance in the pharmaceutical field." Id., page 2. Such products are recognized as "providing a stable, predetermined concentration of a drug in the small intestine, without requiring close monitoring [*3] and frequent re-administration. See id. One common method of achieving sustained release is to "providee a sustained release matrix, such as a fat, a wax, or a polymeric material intermixed with the active ingredient in the tablet itself." Id.

The specification discloses "a composition comprised of acarbose and a sustained release polymeric matrix . . . [and] a method of treating a patient to stimulate weight loss, such method comprised of administering an acarbose formulation to the patient. The acarbose formulation may be mixed with a delayed release matrix, or alternatively may be mixed with a sustained release matrix." Id. The specification "propose[s] that constant levels of acarbose . . . will produce constant inhibitory activity against the digestion of oligosaccharides, thus inhibiting the production of simple sugars. If the utilization of carbohydrates is inhibited, body fat will be used for energy, thus producing weight reduction." Page 5. The specification provides a working example of weight loss produced by acarbose administration in combination with a diet-and-exercise regimen. See page 10.

Discussion

The claims stand or fall together with respect to [*4] each rejection. See the Appeal Brief, page 3. Thus, claims 16-27 will stand or fall with claim 15. Claims 43 stands or falls separately. Claim 15 is directed to a composition consisting essentially of a mixture of acarbose and a sustained release matrix. Claim 43 is directed to a method of stimulating weight loss comprising administering "an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor."

The examiner rejected claim 43 as anticipated by Rosner, and rejected claims 15-27 as anticipated by either Bremer or Patel.

1. Rosner

The examiner rejected claim 43 "under 35 U.S.C. 102(a) as being anticipated by Rosner," reasoning that Rosner "discloses a method of controlling weight in a human comprising administering to the human acarbose at meals with food containing carbohydrate, which anticipates the method of instant Claim 43." Examiner's Answer, pages 5 and 6.

Appellant argues that Rosner is not prior art under 35 U.S.C. § 102(a), because it issued on May 14, 2002, after the filing date of the present application. See the Appeal Brief, pages 3-4. n1 The examiner's [*5] response is that "the invention of the Rosner patent was known or used by others in this country before the filing date of the instant application, as suggested by the filing date of the Rosner patent dated August 2, 1999." Examiner's Answer, page 6.

n1 Appellant also argues that Rosner does not anticipate because it does not disclose an acarbose "formulation", as that term is defined in the specification. This argument is addressed below to the extent that it is relevant to the new ground of rejection entered in this opinion.

We agree with Appellant that Rosner is not available as prior art under 35 U.S.C. § 102(a). "The statutory language, 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." *Carella v. Starlight Archery*, 804 F.2d 135, 139, 231 USPQ 644, 646 (Fed. Cir. 1986). As Appellant points out, Rosner was not accessible to the public, and therefore not available as prior art under 35 U.S.C. § 102(a), until it issued as a patent.

Since Rosner did not [*6] issue until after the filing date of the instant application, it does not qualify as prior art under § 102(a). The correct statute for applying a patent that was filed before, but issued after, a given application filing date is 35 U.S.C. § 102(e). See *In re Lund*, 376 F.2d 982, 988, 153 USPQ 625, 630 (CCPA 1967) ("It is, of course, in-

controvertible that a description of an invention of another in an application filed before an applicant's date of invention, upon which application a patent is issued, constitutes a bar to the issuance of a valid patent for the same invention, *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 46 S.Ct. 324, 70 L.Ed. 651 (1926), codified by § 102(e)."). See also *id.* at 992 n.12, 153 USPQ 625, 633 n.12 ("Inasmuch as § 102(e) makes a description in a patent available as evidence of prior knowledge as of the effective filing date of the application on which the patent issues, it should be regarded as an exception to the general rule that prior knowledge must be public in order to defeat another's [*7] patent rights.").

2. Bremer

The examiner rejected claims 15-27 as anticipated by Bremer, on the basis that Bremer "discloses glucosidase and/or amylase inhibitors that can be manufactured as pharmaceutical compositions for the combined use with a lipase inhibitor." Examiner's Answer, pages 4-5. The examiner pointed out that Bremer suggests acarbose as one of the inhibitors that can be included in the disclosed compositions, and concluded that the "pharmaceutical composition that can be used to treat obesity of the Bremer et al[.] patent anticipates the instantly claimed chemical composition used to stimulate weight loss in a patient." *Id.*, page 5.

Appellant argues that the claims use the transitional phrase "consisting essentially of", and therefore do not encompass compositions (such as Bremer's) that include a lipase inhibitor along with acarbose. Appeal Brief, pages 10-11. In response, the examiner argues that the addition of a lipase inhibitor to an acarbose-containing composition would not change the "basic and novel characteristics" of the composition, because "there is no indication in the Bremer et al[.] patent that the presence of the lipase inhibitor in the composition [*8] of the Bremer et al[.] patent alters the chemical formula of the acarbose and the hydroxypropylmethylcellulose of the Bremer et al[.] patent," and "Appellant has not clearly defined the 'basic and novel characteristics of the instantly claimed composition' in such a way that a lipase would be excluded from the instantly claimed composition." Examiner's Answer, pages 8 and 9.

We agree with Appellant that the instant claims do not read on the composition disclosed by Bremer. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

The question, then, is: what are the basic and novel characteristics of the claimed composition? According to the specification, "acarbose is an inhibitor of the saccharase enzyme complex," which "delays the digestion of ingested carbohydrates." Pages 1 and 4. The other required component of the claimed composition, a sustained [*9] release matrix, is disclosed to "provide[] substantially constant release of acarbose over a pre-determined period of time." Page 2. Thus, we conclude that the basic and novel characteristics of the claimed composition are (1) inhibition of the saccharase enzyme complex, (2) over an extended period of time.

The basic and novel characteristics of the claimed composition do not include inhibition of lipase enzymes. Thus, the addition of a lipase inhibitor would materially affect the basic and novel characteristics of the claimed composition. The claims do not read on the compositions disclosed by Bremer, which all contain a lipase inhibitor. The rejection under 35 U.S.C. § 102(b) is reversed.

3. Patel

The examiner rejected claims 15-27 as anticipated by Patel, on the basis that Patel

discloses a pharmaceutical composition that comprises surfactants and a hydrophilic therapeutic agent (see abstract), whereby the hydrophilic therapeutic agent may be selected as acarbose (see column 31, lines 57 and 58). Patel . . . discloses that the pharmaceutical compositions may be in dosage forms, whereby the dosage forms can be designed for extended release, [*10] which can be effected by a coated matrix composition. . . . Examples of cellulose derivatives that can be used to form the coating composition . . . [include] hydroxypropyl methyl cellulose succinate.

Examiner's Answer, page 3.

Appellant argues that Patel does not anticipate claims 15-27 because, among other things, Patel does not disclose a formulation combining acarbose and a sustained-release matrix. Rather, Appellant argues, Patel discloses unit dosages (e.g., tablets) coated with an extended-release coating. See the Appeal Brief, pages 7-9. Appellant argues that a coating changes the location of release of the active agent (from stomach to lower gastrointestinal tract) but does not provide a steady release of acarbose over an extended period of time, as a sustained-release matrix does. See *id.*, page 8.

We agree with Appellant. Anticipation under 35 U.S.C. § 102 requires identical disclosure of the claimed invention in the prior art. See *Gechter v. Davidson*, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) ("Under 35 U.S.C. § 102, every limitation [*11] of a claim must identically appear in a single prior art reference for it to anticipate the claim."); "Every element of the claimed invention must be literally present, arranged as in the claim." *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The instant claims are directed to a mixture consisting essentially of acarbose and a sustained release matrix. See claim 15. The specification clearly distinguishes between a sustained release coating and a sustained release matrix:

Sustained release is achieved by a variety of methods. Two common methods are: 1) providing a sustained release coating upon tablets or microspheres wherein slow release of the active ingredient occurs via either gradual permeation through or gradual breakdown of this coating; or 2) providing a sustained release matrix, such as a fat, a wax, or a polymeric material intermixed with the active ingredient in the tablet itself.

See page 3, lines 20-24 (emphasis added).

The claim limitations requiring the presence of a sustained release matrix, which must be mixed with the acarbose, shows that the claims [*12] are limited to acarbose formulations made according to the second method described in the specification. According to the examiner, however, Patel discloses only "dosage forms [that] can be designed for extended release, which can be effected by a coated matrix composition." Examiner's Answer, page 3 (emphasis added). Thus, the claims do not read on the compositions disclosed by Patel.

We also note that the examiner has not pointed to any specific composition disclosed by Patel that contains both of the ingredients required by instant claim 15. Rather, the examiner pointed to a passage in Patel that disclosed acarbose as one of numerous possible active agents that could be used, and pointed to another passage in Patel teaching that the disclosed formulations could be made into coated dosages. The amount of picking-and-choosing needed to distill the claimed composition from the reference disclosure seems incompatible with a rejection for anticipation; at best, the reference would seem to suggest (in the § 103 sense) the composition cited by the examiner as the basis of the rejection. n2

n2 We are not suggesting that the examiner should reject the claims as obvious in view of Patel, only that the lack of specificity in the reference would seem to be another problem facing a rejection for anticipation. [*13]

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claim 43 is rejected under 35 U.S.C. § 102(e) as anticipated by Rosner. Claim 43 is directed to a method of stimulating weight loss comprising administering "an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor."

Rosner discloses a method "to control weight gain, to provide weight loss and for the prevention or treatment of diabetes." Column 2, lines 11-13. The method comprises ingesting acarbose with meals that contain carbohydrates. See column 1, lines 8-10; claims 1 and 3. Rosner does not teach administering the acarbose in combination with a lipase inhibitor, and therefore the patent is most reasonably interpreted to disclose an acarbose formulation that does not include a lipase inhibitor.

Appellant argues that Rosner does not disclose an acarbose "formulation", as called for in the claim, because "as defined in the specification and recited in the claims, an acarbose formulation is a mixture of acarbose and a sustained release matrix. (Ex. 1, pg. 1, lns 18-20)." Appeal Brief, [*14] page 4. n3

n3 Appellant also argued that Rosner is not prior art under 35 U.S.C. § 102(a). As explained above (pages 3-5), Appellant is correct, but the reference is prior art under 35 U.S.C. § 102(e).

This argument is not persuasive. We have reviewed the entire specification, including the portions cited by Appellant, but have found no definition of the phrase "acarbose formulation" that shows an intention to limit the phrase to formulations containing a sustained release matrix. On the contrary, a acarbose formulation containing a sustained-release matrix is invariably referred to as a "sustained release formulation", or something similar. See, e.g., the title of the application ("Method and composition for controlled release acarbose formulations"); page 2, line 15 ("slow release acarbose formulation"); page 2, line 18 ("sustained release acarbose formulation"); page 6, line 22 ("sustained release formulation of acarbose"); page 10, line 23 ("acarbose delayed release formulation"). In addition, on page 3, lines 7-8, the specification discusses an "acarbose formulation" that may be mixed with, and therefore [*15] necessarily does not include, a sustained release matrix.

We therefore reject Appellant's strained interpretation of the claim language. The claim reads on administration of acarbose alone and is anticipated by Rosner.

Summary

Neither Bremer nor Patel identically disclose the compositions defined by claims 15-27; we therefore reverse the rejections of these claims. We also reverse the examiner's rejection of claim 43, but enter a new ground of rejection of that claim under the correct statutory provision.

REVERSED, 37 CFR § 1.196(b)

Legal Topics:

For related research and practice materials, see the following legal topics:

Patent LawAnticipation & NoveltyElementsPatent LawInequitable ConductEffect, Materiality & ScienterGeneral OverviewPatent LawU.S. Patent & Trademark Office ProceedingsExaminationsGeneral Overview